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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/055,818      04/06/98      GUTIERREZ-ROCCA      J      I-132D

HM12/0915  
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EXAMINER

RAYMOND, R

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

09/15/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/055,818**

Applicant(s)  
**Gutierrez-Rocca et al.**

Examiner  
**Richard L. Raymond**

Group Art Unit  
**1624**



☒ Responsive to communication(s) filed on Aug 17, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-117 is/are pending in the application.

Of the above, claim(s) 53-117 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-52 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13, 4, 7, 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

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--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Claims 53-117 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 12. It is maintained that the elected compositions can have uses other than in the process of Group II. Accordingly, the requirement is repeated and made final.
2. Pursuant to the requirement for election of species, applicants have elected the species of the combination of a taxane and saturated polyglycolized glycerides. Claims 1-52 are readable thereon.

### ***Claim Rejections - 35 USC § 112***

3. Claims 1, 2, 8-20 and 25-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific surfactants and emulsifiers, does not reasonably provide enablement for any and all carriers defined merely by having an HLB value of at least about 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Note that an unpredictable and unexpected use, absorption of a taxane, is involved. Representative exemplification for the scope of the present carriers is not seen present.

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***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Bastard et al., Agharkar et al., Bobee et al., Schwartz et al., Kaufman et al., Benet et al., Trissel, and Andersson, cited by applicants. The present invention is to a composition of a taxane and a carrier having an HLB value at least about 10. The carrier is further defined in dependent claims as various surfactants and emulsifiers. The cited references all disclose taxanes compositions containing carriers, polyethylene glycol or hydrogenated castor oil (Bastard et al.), polyoxyethylated castor oil (Agharkar et al.), surface-active agents (Bobee et al.), surfactants (Schwartz et al., Kaufman et al. and Trissel), essential oils (Benet et al.), and polyethylene glycol solutions (Andersson). In the absence of a clear delineation of the present compositions, particularly with respect to the broadly defined carriers, and a showing of unexpected properties resulting from any such differences, no patentable significance is seen in the present selection.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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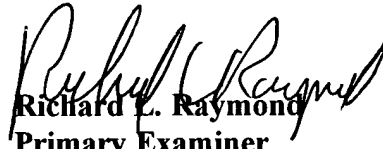
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Raymond whose telephone number is (703) 308-4523. The examiner can normally be reached on weekdays from 9:30 AM to 6:00 PM.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

rr  
September 14, 2000

  
**Richard L. Raymond**  
**Primary Examiner**  
**Art Unit 1624**